# Effect of Locking Mechanism on Fluid and Particle Flow Through Modular Acetabular Components

Brief title: Particle flow through modular components

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## INTRODUCTION

Osteolysis remains a major concern in joint replacement surgery. Periprosthetic bone loss secondary to osteolysis can cause loosening and failure in otherwise well implanted components. Aggressive granulomatous lesions were first thought to be a consequence of host reaction to polymethylmethacrylate, but when similar osteolytic lesions were found in uncemented joint replacements it became apparent that other factors were involved.[5,6,10,13,15] It is now generally accepted that submicron polyethylene wear debris is an important factor contributing to the synovitis and synovial reaction that contributes to osteolysis.[1,3,9,15] Improved bearing surfaces such as ceramics and ultra-high molecular weight polyethylene have reduced polyethylene wear while enhanced fixation of polyethylene liners into metal cups has reduced significant backside wear and disassociation of the liner from the cup. However, even with the most modern designs a certain amount of polyethylene debris is liberated due to wear. Early reports of osteolytic lesions in cementless acetabula suggested that the screw holes acted as conduits for debris migration into the pelvic bone stock.[8,12] Debris generated at the articular surface can migrate between the liner and shell, and gain access to the pelvic bone stock through the screw holes. Loss of bone support secondary to osteolysis can lead to loosening and eventual failure of the acetabular component. Recent design modifications to help prevent migration of wear debris into the acetabular bone stock include sealing the screw holes with modular caps or eliminating the screw holes altogether. However, the

metal shell often requires augmented fixation, and screws inserted through the shell offer a simple solution to an otherwise complex problem. If the interface between the polyethylene and the metal shell were sealed, then the joint fluid and articular wear debris would not have access to the screw holes and the use of screws would be safe.

The purpose of this study was to evaluate the currently available acetabular components in their capacity to allow submicron debris to enter the interface between the metal shell and the polyethylene liner and to test a new mechanism designed to seal this interface. We hypothesized that two thin peripheral ridges on the polyethylene cup could be fit tightly against the inner surface of the metal shell to seal the interface between the cup and liner.

## Methods and Materials

### Components

Six modular acetabular components were evaluated: a Precision Osteoloc (Howmedica, Rutherford, NJ), a Trilogy (Zimmer, Warsaw, IN), a Reflection (Smith & Nephew, Memphis, TN) with a tapered metal insert covering the screw hole, a Reflection with a taper-head screw, and two different versions of the Micro-Seal (Whiteside Biomechanics, St. Louis, MO) component. The inner rim of the Micro-Seal shell has a 1.5° angled taper which forms a 10 mm wide entrance for the polyethylene into the shell. The corresponding surface of the polyethylene insert has a matching taper and two thin peripheral ridges that engage the tapered surface of the metal shell as the polyethylene is inserted. (Figure 1) The combination of tapered surface in the metal cup and peripheral ridges on the liner is designed to provide a water-tight seal between the polyethylene and the metal cup that would prevent migration of debris from the joint surface through the cup-liner interface. Rotational stability is achieved by way of three peripheral locking tabs on the polyethylene liner with corresponding slots in the cup. The Micro-Seal cup was manufactured with one screw hole for this study. The other Micro-Seal polyethylene was identical except for the absence of the sealing ridges.

One Reflection component was tested with a tapered metal insert over the collecting screw hole. Another Reflection component was tested with a 40 mm taper head screw placed through the collecting screw hole and driven into a 1cm x 1cm x 4cm block of wood inside the collecting chamber.

The screw was placed at an angle perpendicular to the surface of the shell. The wood was in contact both with the bottom of the collection chamber and the bottom of the acetabular component. A linearly variable differential transducer (LBB-375-PA-060, Schaevitz, Pennsauken, NJ) was used to monitor micromotion to ensure less than 100 microns of motion between the screw head and the shell under test conditions.

**Test Setup**

The acetabular cup for each trial was mounted with epoxy to a sealed collecting chamber at a 25° angle to horizontal. All screw holes except one were filled with epoxy. A femoral head was cemented with polymethylmethacrylate into the polyethylene liner and the apparatus was placed into an servohydraulic testing device (Instron 8501, Instron, Canton MA). Axial preload of 270 N was applied and the housing was secured to the base with four quadrant screws. Cyclical axial load of 270– 2700 N was applied with a torsional load of ± 2.5 Nm in a sinusoidal waveform at 10 Hz. The components were run dry for 1,000 cycles under test conditions to ensure proper seating of the liner into the cup. A sealed chamber was placed over the acetabular component and secured to the collecting chamber with silicone sealant. (Figure 2)

Polystyrene microspheres ($1.87 \times 10^{14}$ particles/mL) with an average diameter of 0.5 microns (Structure Probe, Inc., PA) were placed in 2 mL of double-deionized water and inserted into the sealed chamber encasing the acetabular component. The pressure within the chamber was maintained at 300 mm water pressure by means of a fluid column. The only channel

between the fluid chamber above and the collecting chamber below was through the cup-liner interface. Fluid and microspheres present in the collecting chamber were harvested after 1,000,000 cycles. If no fluid was present, the inside of the collection chamber was irrigated with 20cc of double-deionized water which then was collected and analyzed.

**Specimen Analysis**

The collected sample was filtered through a 0.2 micron pore filter. The filters were prepared for scanning electron microscopic evaluation (JEOL 35, JEOL, Peabody, MA) by air drying for 48 hours in individual containers. They were affixed to aluminum mounts by copper adhesive tape and sputter coated with gold and palladium to impart conductivity. They were examined individually under electron microscopy at low (1,000x-2000x) and high (12,000x) magnification for evidence of microspheres.

## RESULTS

After 1,000,000 cycles, water and polystyrene microspheres were isolated in the collecting chamber of the Precision Osteoloc, the Trilogy, the Reflection with the taper-head screw, and the Micro-Seal cup without the peripheral ridge. In these components, no resistance to the flow of fluid was apparent and the collecting chambers quickly filled with water. The filtrate of these trials was a fine white powder. SEM analysis showed this powder to consist of polystyrene microspheres (Figure 6). The collection chamber of the Reflection with the tapered metal insert over the screw hole and the Micro-Seal with the intact peripheral seal were dry after 1,000,000 cycles . The irrigant of these two trials was devoid of microspheres (Figure 7).

The inside of the metal shells and the backside of the polyethylene inserts for all trials except the Micro-Seal with the intact peripheral seal had evidence of microspheres in the form of a fine white powder. In the Micro-Seal with the intact peripheral ridges, the cup-liner interface was completely dry after 1,000,000 cycles.

## DISCUSSION

Osteolysis is currently the most important issue in total hip arthroplasty. Loosening secondary to osteolytic bone loss is a frequent cause of failure in otherwise well implanted components.[5,11] Although wear characteristics in total hip arthroplasty have improved with better design and improved bearing surfaces, the liberation of particulate wear debris is inevitable. Polyethylene debris particles produced in total hip arthroplasty have been estimated to number in the billions per year.[1,2,7]

These wear particles can then migrate within the effective joint space to areas of exposed bone where they can induce an osteolytic response.[11] The osteolytic potential of submicron polyethylene debris is well documented.[4,9,15] Extracellular and intracellular polyethylene particles are present in histological samples taken from focal areas of osteolysis around cementless cups, including osteolytic cysts around screw holes.[2,6,12,13]

In total hip arthroplasty, polyethylene wear debris is produced at the articular surface and also on the backside of the liner. Significant backside wear is reduced with effective peripheral locking mechanisms[16] and therefore the majority of debris is generated at the articular surface.[7,13,17] In cementless acetabula the areas of bone susceptible to debris migration include the bone at the periphery of the component and that underlying the screw holes.[8,11] Debris migration at the periphery of the metal shell is effectively blocked by fibrous ingrowth.[2,11,14] Debris generated at the articular surface can gain access to the pelvic bone stock underlying the acetabular component by migrating between the cup and liner and through

the screw holes. As shown in this study this phenomenon occurs even if screws are used. Acetabular components without screw holes are available, however they preclude the use of screws and thus limit surgical options for fixation. In this study all of the components, except the Micro-Seal with the intact peripheral sealing mechanism, allowed microspheres and fluid to enter the cup/liner interface and thus the particles had access to the underlying bone through the screw holes. The tapered metal insert provided an effective seal over the screw hole in the Reflection implant, however in the presence of screws, debris and fluid flowed freely through the screw hole. The Micro-Seal component with the peripheral seal had no evidence of microspheres penetrating beyond the seal. With an effective peripheral seal, screws and screw holes in the shell can be used without fear of debris migration into the underlying pelvic bone stock. When coupled with an effective polyethylene locking mechanism that minimizes backside wear of the liner and a contiguous porous coating around the periphery of the metal cup, the acetabular bone stock is much less susceptible to osteolytic attack.

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# LEGENDS

Figure 1

Photograph of a locking tab and the two peripheral ridges on the Micro-Seal polyethylene liner. The peripheral ridges were removed with a scalpel from one liner for the purpose of this study.

Figure 2

Photograph of the test set-up showing the sealed upper chamber, which is filled with water and microspheres, and the lower collecting chamber. The test apparatus was held in place with four quadrant screws. One hundred millimeters of water pressure was supplied through the plastic tubing.

Figure 3

The 0.5 micron microspheres are evident in this SEM image of a filter at 12,000x.

Figure 4

No microspheres are seen on this SEM image of a filter from the Micro-Seal component whose liner had intact peripheral ridges. The dark areas are holes in the filter. 20,000X.